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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,580	06/26/2003	Roberto C. Beretta	015445-9002-01	5786

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,580	BERETTA ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-41* is/are pending in the application.

4a) Of the above claim(s) *19 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 18, 20-32, 34-36, 40 and 41* is/are rejected.

7)☒ Claim(s) *37-39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II (claims 17-41), a calcium coagulator and a stem cell as the therapeutic agent in the reply filed on 4/19/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/19/06.

Claims 17, 18, 20-32 and 34-41 are presented for examination.

Specification

The use of the trademarks TEFLON and DACRON (p. 12) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 23, 27-32, 36 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jahn (US 5,275,731) in light of Brandwein et al. (US 6,544,751).

Jahn discloses a blood collection and separation device comprising a multi-chamber collection assembly having a longitudinal axis about which the assembly can rotate and be subjected to centrifugal force. A porous separating body at one axial end of one chamber connects with a second chamber and allows flow of the lighter fraction of the blood from one chamber to the second chamber during centrifugation, but blocks the flow of the heavier red blood cell fraction (abstract, col. 6, lines 11-46). The device comprises a blood collection container (this is the first chamber) onto which is placed the second chamber 8. Between the second chamber and the collection device is a porous filter means 7. The porous filter is a hydrophobic material (col. 5, lines 4-8). The assembly is placed in an axial centrifuge (Fig. 4). When the assembly rotates, the heavier cells move to the wall of the collection chamber. The filter allows the lighter cells to pass through to the upper (second) chamber 8 (see Figs. 5 and 6). The upper (second chamber) 8 can further comprise clot activators (col. 6, line 22). This disclosure meets the limitations of instant claim 17 because Jahn's device is used in an axial centrifuge. Jahn's device comprises two chambers, a filter that separates the chambers and the second chamber comprises a coagulator. The filter meets separating medium limitation of claim 23. The circumferences of the first and second chambers are substantially the same, as shown by Figs. 5-6, as in instant claim 28.

Jahn discloses an embodiment wherein the device comprises a blood collection portion that is connected to the filter and blood collection chamber wherein the orientation is reversed such that the first chamber is on top of the second chamber that collects the light cell fraction (see Figs. 14-15). As previously discussed, the second chamber comprises the coagulant. This embodiment meets the limitations of instant claims 27 and 32. Figs. 14-15 show that the circumference of the first chamber is less than that of the lower second chamber, as in instant claims 29 and 32. Figs. 14 and 15 show that the first chamber has an upper and a lower portion, as in instant claim 36.

Brandwein et al disclose that whole blood inherently contains rare cells such as stem cells (col. 2, lines 50-60). This disclosure demonstrates that a whole blood sample that is contained in the blood collection container (this is the first chamber) taught by Jahn *supra* inherently contains stem cells. Claims 30, 31 and 40 recite only that a therapeutic enhancing agent (stem cells are the elected specie) is present in either the primary or secondary chamber. The presence of whole blood in the blood collection chamber taught by Jahn means that stem cells are present since they are an inherent part of a whole blood sample.

The disclosure by Brandwein et al. is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the definition of a kit. MPEP 2131.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18, 20, 22-32, 34, 36, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahn (US 5,275,731), as applied to claims 17, 23, 27-32, 36 and 41, in view of Smith et al. (US 5,667,963).

The disclosure by Jahn is discussed *supra.*

Jahn does not teach that the primary chamber (the blood collection chamber) contains an anticoagulant, that the coagulator comprises calcium, or the type of filter and its barrier properties.

Smith et al. disclose that it is desirable to combine blood samples with an anticoagulant for the purpose of the separation of said blood into component cells when a thixotropic gel barrier is used. If the container for separation is a centrifuge tube then the thixotropic barrier is placed midway to form an upper and lower chamber. The solution containing the anticoagulant is placed in the upper chamber that receives the blood sample (col. 6, lines 7-21). Smith et al. particularly recommend a citrate buffer to cleanly fractionate the cell types. Smith et al. teach that a variety of thixotropic gels are known in the art. They are water insoluble and commonly formulated with a polysiloxane or polyester and them chemically modified to make a hydrophobic product (col. 8, lies 45-54). Smith et al. also disclose the use of multiple thixotropic barriers at different positions in the blood separator device (col. 8, lines 43-60). Smith et al. disclose that a container with a thixotropic gel was used to fractionate citrated whole blood in a centrifuge at 1,500 g (col. 10, lines 39-53). Smith et al. also state that calcium plays a key role in blood coagulation and that a calcium agent can be added to anti-coagulated blood to achieve coagulation (col. 3, lines 49-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a thixotropic gel comprising a siloxane and polyester as the filter in the blood collection and separation device taught by Jahn. The ordinary artisan would have been motivated to do so because Jahn teaches that the barrier to red blood cells should be hydrophobic. Smith et al. fulfill this need by teaching that thixotropic barriers are well known in centrifugation methods using at least 1,500 g, as hydrophobic barriers for the separation of red blood cells from other blood components. The ordinary artisan would have had a reasonable expectation that a thixotropic barrier could successfully separate RBC's from other cell components in a citrate whole blood sample because they demonstrated this in the example in col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a an anti-coagulant in the primary chamber and to use a calcium salt as the coagulant in the secondary chamber in blood collection and separation device taught by Jahn. The ordinary artisan would have been motivated to do so because Jahn teaches that the employment of an anti-coagulant in the chamber that holds the blood sample improves the fractionation result and that calcium salts are well known coagulating agents. The ordinary artisan would have had a reasonable expectation that the use of an anti-coagulant in the blood sample chamber and the employment of a calcium salt as the coagulant in the secondary chamber would successfully separate RBC's from other cell components in a citrate whole blood sample because they demonstrated this in the example in col. 10.

Claims 17, 18, 20-32, 34-36, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahn (US 5,275,731) in view of Smith et al. (US 5,667,963), as applied to claims 17, 18, 20, 22-32, 34, 36, 40 and 41, in further view of Goldstein (US 6,114,135).

The combined disclosures of Jahn and Smith et al. are discussed *supra.*

The combined disclosure do not disclose any specific calcium salts for use as coagulating agents.

Goldstein discloses that calcium chloride and calcium gluconate are well known coagulating agents especially for the coagulation of a blood sample that has been previously anti-coagulated with citrate (col. 11-12, bridging).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ calcium chloride or calcium gluconate as the coagulating calcium salts in the device taught by the combined disclosure of Jahn and Smith et al. The ordinary artisan would have been motivated to do so because Smith et al. recognize that calcium salts are well known coagulating agents and Goldstein fulfills this recognition by teaching specific calcium salts that are well known to fulfill this need. The ordinary artisan would have had a reasonable expectation that calcium gluconate and calcium chloride

would be effective coagulating agents in the device taught by the combined disclosures because either salt supplies calcium that binds citrate in an anti-coagulated blood sample.

Claims 37-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1651

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